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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,767	09/29/2003	Takashi Kitaoka	018961-065	7544
21839	7590	04/05/2005	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			PRONE, CHRISTOPHER D	
		ART UNIT	PAPER NUMBER	
		3738		

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/671,767	KITAOKA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christopher D Prone	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 29 September 2003.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-17 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-17 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 29 September 2003 is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/24/04 9/29/03.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

## DETAILED ACTION

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, "the stent with two or more links provided between an adjacent pair of annular units" described in claim 6, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

Claim 8 is objected to because of the following informalities: a typographical error. The first line of claim 8 reads, "the indwelling according to," but should read "the indwelling stent according to." Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 9, 11-15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 5,931,867 Haindl.

In reference to claims 1 and 12 Haindl discloses the same invention being a living organ dilator and an indwelling stent formed in a substantially tubular shape, wherein said stent comprises annular units arranged in an axial direction of said stent, each of said annular units comprises a plurality of annular elements referenced as element 1, an opening in a central portion thereof referenced as element 2, adjacent portions of said annular elements are joined to each other through a joint, adjacent annular units being interconnected at their joints by at least one link, said annular elements in each said annular unit are so arranged that one of each adjacent pair of said annular elements is located on the proximal end side in the axial direction of said stent, end portions of each said annular unit are projected zigzag, said zigzag projected

end portion of said annular unit is in the state of penetrating into the adjacent annular unit, and said joints in each said annular unit are substantially parallel to the stent axis shown in figures 1-2 of Haindl. Haindl teaches the use of a balloon dilator in column 1 on lines 35-38.

In reference to claims 2, 3, and 14 Haindl discloses the same invention wherein the stent comprises at least two annular units and each annular unit comprises at least four annular elements shown in figures 1-2 of Haindl

In reference to claims 4 and 15 Haindl discloses the same invention wherein the link is substantially parallel to stent axis referenced as element 5 and shown in figures 1-2 of Haindl.

In reference to claim 6 Haindl discloses the same invention wherein two or more links referenced as element 4 are provided between an adjacent pair of annular units shown in figure 2 of Haindl.

In reference to claims 7 and 17 Haindl discloses the same invention wherein each said link referenced as element 4 is so disposed as not to be continuous with the adjacent link shown in figure 2 of Haindl

In reference to claim 9 Haindl discloses the same invention wherein the annular elements are not aligned substantially rectilinearly with respect to the axial direction of said stent shown in figures 1-2 of Haindl.

In reference to claims 11 and 13, which are product by process claims, the invention of Haindl meets all the structural requirements claimed. Therefore it is inherent that the invention of Haindl is produced with a predetermined outside diameter

by use of a plastically deformable material-made pipe and then reduced in diameter by compressing from outside.

Note: In regard to claims 11 and 13, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (MPEP 2113).

Claims 1, 5, 12, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 5,695,516 Fischell.

In reference to claims 1 and 12 Fischell discloses the same invention being a living organ dilator and an indwelling stent formed in a substantially tubular shape, wherein said stent comprises annular units arranged in an axial direction of said stent, each of said annular units comprises a plurality of annular elements referenced as element 14, an opening in a central portion thereof, adjacent portions of said annular elements are joined to each other through a joint referenced as element 18, adjacent annular units being interconnected at their joints by at least one link, said annular elements in each said annular unit are so arranged that one of each adjacent pair of said annular elements is located on the proximal end side in the axial direction of said stent, end portions of each said annular unit are projected zigzag, said zigzag projected end portion of said annular unit is in the state of penetrating into the adjacent annular unit, and said joints in each said annular unit are substantially parallel to the stent axis shown in figures 1-3 of Fischell. Fischell teaches the use of a balloon dilator in column 2 on lines 17-19.

In reference to claims 5 and 16 Fischell discloses the same invention wherein the stent comprises a radiopaque material marker described in column 3 on lines 22-29.

Claims 1, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 5,807,404 Richter.

In reference to claim 1 Richter discloses the same invention being an indwelling stent formed in a substantially tubular shape, wherein said stent comprises annular units arranged in an axial direction of said stent, each of said annular units comprises a plurality of annular elements referenced as elements 4-7, an opening in a central portion thereof referenced as element 3, adjacent portions of said annular elements are joined to each other through a joint referenced as elements 8-11, adjacent annular units being interconnected at their joints by at least one link, said annular elements in each said annular unit are so arranged that one of each adjacent pair of said annular elements is located on the proximal end side in the axial direction of said stent, end portions of each said annular unit are projected zigzag, said zigzag projected end portion of said annular unit is in the state of penetrating into the adjacent annular unit, and said joints in each said annular unit are substantially parallel to the stent axis shown in figures 1-11 of Richter. Richter teaches the use of a balloon dilator in column 2 on lines 17-19.

In reference to claim 8 Richter discloses the same invention wherein said annular elements are aligned substantially rectilinearly and parallel with respect to the axial direction of said stent shown in figure 1 of Richter.

In reference to claim 10 Richter discloses the same invention wherein an end portion, located on the outer side, of each of said annular elements located at both ends of said stent is roughly semi-elliptic in shape referenced as element 10' shown in figures 1-11 of Richter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-6085. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDP

  
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